PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 141-446PCT	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2004/004112	International filing date (day/month/year) 12 February 2004 (12.02.2004)	Priority date (day/month/year) 19 September 2003 (19,09,2003)
International Patent Classification (8t See relevant information in Form I	h edition unless older edition indicated) PCT/ISA/237	
Applicant ANDRX LABS LLC		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).					
2.	This REPORT consists of a total	of 4 sheets, including this cover sheet.				
		ace to the written opinion of the International Searching Authority should be read as a reference port on patentability (Chapter I) instead.				
3.	This report contains indications re	elating to the following items:				
	Box No. I	Basis of the report				
	Box No. II	Priority				
	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability				
	Box No. IV	Lack of unity of invention				
	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement				
	Box No. VI	Certain documents cited				
	Box No. VII	Certain defects in the international application				
	Box No. VIII	Certain observations on the international application				
4.		numicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but akes an express request under Article 23(2), before the expiration of 30 months from the priority				

	Date of issuance of this report 28 February 2007 (28.02.2007)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Athina Nickitas-Etienne
Facsimile No. +41 22 338 82 70	e-mail: pt04.pct@wipo.int

PATENT COOPERATION TREATY

rom the	ONAL SEARCH	ING AUTH	DRITY		PCT	REC'D	16	AUG	2004
To: MARTIN P. ENDRES				WIPO					
HEDMAN & COSTIGAN, P.C. 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036		WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY							
					(PCT Rule 43bis				
				Date of mailing (day/month/year)		124	ŲĞ,	,0U	
Applicant's	or agent's file re	ference		FOR FURTHER	ACTION See paragraph 2 belov	w ·			
141-446 Po	at application No.		International filing date	(day/month/year)	Priority date (day/m	onth/year)			
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1			or both national classifica		,				
Applicant	51K 9/28, 9/16 ar	id US CI.: 4	241414, 450						
ANDRX I	ABS LLC								ᅱ
1. This o	pinion contains is	dications re	lating to the following ite	ms:	1				
	Box No. I	Basis of th	e opinion						
	Box No. II	Priority							
	Box No. III		ishment of opinion with a	egard to novelty, inv	rentive step and moust	tiar abbirc	ношту		
	Box No. IV	Lack of un	ity of invention			-ton on in	Andrial		
	Box No. V	Reasoned applicabili	statement under Rule 43b ty; citations and explanat	is .1(a)(i) with regard ions supporting such	statement	sup or m			- [
	Box No. VI		currents cited						1
	Box No. VII		efects in the international		-				-
	Box No. VIII	Certain of	oservations on the interna	tional application					
2, FUI	THER ACTIO	N		a de objeto and	II he considered to be	a written	opinio	n of t	ie i
2. FURTIBLE ACATON If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("PEA") except that this does not apply where the applicant chooses an Authority other than this one to be the PEA and the chosen PEA has notified the International Bureau under Rule 66.1bin (b) that written opinions of this International Scarching Authority will not be so considered.						<i>5</i>)			
If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the capitation of 3 mentles from the date of mailing of Form PCTIFSA/200 or before the expiration of 22 mentle from the priority date, whichever expires later.						he of			
For	For further options, see Form PCT/ISA/220.								
3. For further details, see notes to Form PCT/ISA/220.									
Name and mailing address of the ISA/ US Authorized officer Authorized officer					1	_			
Mali Stop PCT, Attn: ISA/US Commissioner for Patents				Robert M. Joynes J. Roberts for					
P.O. Box 1450 Alexandria, Virginia 22313-1450				Telephone No. (571) 272-1600					
Form PC	Facsimile No. (703) 872-9306 Form PCT/ISA/237 (cover sheet) (January 2004)								

PCT/USZ004/00411Z

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

1	International application No.
_	PCT/US04/04112

,	INTERNATIONAL SEARCHING ACTIONAL	101/00017111					
Box No.	Box No. I Basis of this opinion						
 With regard to the language, this opinion has been established on the basis of the international application in the language in which 							
it was fil	it was filed, unless otherwise indicated under this item. This opinion has been established on the beais of a translation from the original language into the following language—which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).						
2 With ra	which is the staggage to a commence of the staggard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:						
	ype of material						
,	a sequence listing						
Ī	table(s) related to the sequence listing						
b. f	format of material	,					
	in written format	İ					
[in computer readable form						
c. t	time of filing/furnishing						
	contained in international application as filed.						
ſ	filed together with the international application in computer rea	dable form.					
l i	furnished subsequently to this Authority for the purposes of sear	ch.					
	In addition, in the case that more than one version or copy of a sec filed or furnished, the required saturateurs that the information in the the application as filed or does not go beyond the application as filed,						
4. Additio	onal comments:						
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PC1/U52004/004112

WRITTEN OPINION OF THE

International application No. PCT/US04/04112

	ARCHING AUTHORIT		
Box No. V Reasoned statement applicability; citation	under Rule 43 bis.1(a)(i) is and explanations suppo	AUTHORITY 3 bit. I(a)(f) with regard to novelty, inventive step or industrial attors supporting such statement Claims 1-34 YES Claims NONE NO	
Statement Novelty (N)			
Inventive step (IS)	Claims Claims	1-34	YESNO
Industrial applicability	(IA) Claims		YES NO

Citations and explanations:

Claims 1-34 meet the criteria set out in PCT Article 39(2)-(3), because the prior art does not teach or fairly suggest a pharmaccurical dosage form where in the controlled release our contains an artityperglycench durg and the coating contains a inheritation described derivative wherein the coating layer is an immediate release layer. The closd references teach this two drug combination but the outside layer is not an immediate release layer. The closd references teach this two drug combination but the outside layer is not an immediate release composition where not less than 53% of the drug is released within 45 minutes but rather a controlled release layer that releases the drug over a longer period of the controlled release.

Claims 1-34 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability as a pharmaceutical formulation because the subject matter claimed can be made or used in industry.

Form PCT/ISA/237 (Box No. V) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/04112

PC(7) A 61K 9/28, 9/16 US Cl. 24/4/14, 490 According to international Patent Classification (IPC) or to both national classification and IPC B FIELD SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 42/4/14, 490 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched of the search	A. CLASSIFICATION OF SUBJECT MATTER						
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